18-02690-E

February 22 2018

US Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE Mail Stop 5100
Washington, DC 20549-5100

Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following:

A copy of: Exhibit 10.2 to the form 10-Q filed by GENEREX BIOTECHNOLOGY CORP on December 11, 2009

In the event confidential treatment has not expired provide the specific date for which confidential treatment is still in effect. I do not need a copy of the order. We authorize up to $61.00 in processing fees. Thank You,

Paul D'Souza
Editor - Deals

Clarivate Analytics Friars House, 160 Blackfriars Road London, UK SE1 8EZ
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paul.dsouza@clarivate.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 22, 2018

Mr. Paul D'Souza
Clarivate Analytics
160 Blackfriars Road
London, UK SE18EZ

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02690-E

Dear Mr. D'Souza:

This letter is in response to your request, dated and received in this Office on February 22, 2018, for Exhibit 10.2 to the Form 10-Q filed by Generex Biotechnology Corp. on December 11, 2009.

The search for responsive records has resulted in the retrieval of 34 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me directly at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Clarissa Anderson

Clarissa Anderson
FOIA Research Specialist

Enclosure

RECOMBINANT HUMAN INSULIN ACTIVE INGREDIENT MANUFACTURING AND SUPPLY AGREEMENT

BETWEEN

GENEREX BIOTECHNOLOGY CORPORATION

AND

SANOFI-AVENTIS DEUTSCHLAND GMBH

DATED: **NOVEMBER 24, 2009**

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RECOMBINANT HUMAN INSULIN ACTIVE INGREDIENT

MANUFACTURING AND SUPPLY AGREEMENT

(RECOMBINANT HUMAN INSULIN COMMERCIAL QUANTITIES)

THIS MANUFACTURING AND SUPPLY AGREEMENT (the "Agreement") is made effective as of November 24, 2009 (the "Effective Date") between:

GENEREX BIOTECHNOLOGY CORPORATION, a Delaware corporation having a place of business at 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2 ("Generex"); and

SANOFI-AVENTIS DEUTSCHLAND GMBH, a company existing under the laws of Germany, located at Industriepark Hoechst, 65926 Frankfurt am Main, Germany (**"SAD"**).

Generex and SAD are individually referred to herein as a "Party" and are collectively referred to herein as the "Parties".

BACKGROUND

A. Generex wishes to engage SAD to perform services for Generex, as more specifically set forth herein, in connection with the manufacturing and supply of Active Ingredient for use in the Product.

B. SAD wishes to perform such services subject to the terms and conditions set forth in this Agreement.

COVENANTS

In consideration of the mutual covenants and promises set forth herein, and intending to be legally bound hereby, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement:

"Acquisition Cost" shall mean the actual invoiced price actually paid by SAD to any Third Party for materials, components and packaging materials required to manufacture and package the Active Ingredient hereunder, including, but not limited to, shipping and handling

costs, taxes and customs duties incurred and paid by SAD to any Third Party in connection with the acquisition of such materials and components, as the case may be.

"Active Ingredient" shall mean Recombinant Human Insulin as manufactured by SAD in accordance with the Active Ingredient Specifications, for use in the Product.

"Active Ingredient Price(s)" shall have the meaning set forth in Article 9 hereof.

"Active Ingredient Specifications" shall mean the specifications for the Active Ingredient attached hereto as Exhibit 4 and made a part hereof, as determined in accordance with the analytical methodology set forth therein, as such specifications may be amended from time to time by mutual agreement of the Parties in accordance with the terms and conditions of the Quality Agreement.

"Affiliate" shall mean any corporation or non-corporate entity which controls, is controlled by, or is under common control with a Party. A corporation or non-corporate entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty percent (50%) of the voting stock of the other corporation or (a) in the absence of the ownership of at least fifty percent (50%) of the voting stock of a corporation or (b) in the case of a non-corporate entity, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable.

"Agreement" shall mean this Manufacturing and Supply Agreement, as it may hereafter be amended or supplemented from time to time in accordance with the terms hereof.

"[Capacity Cap]*" shall have the meaning set forth in Section 2.4 hereof.

"cGMPs" shall mean applicable standards for current good manufacturing practices of active ingredients specified in (i) the ICH Guidelines, and (ii) the FDA's "Guidance for Industry Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients". For clarity, such definition of cGMPs shall not include other country-specific regulatory requirements.

"Certificate of Analysis" shall mean a document, signed by an authorized representative of SAD, certifying the Specifications for, and testing methods applied to, the Active Ingredient, and the results thereof, and which includes the Active Ingredient date of manufacture, date for re-testing or expiration date as appropriate.

"Certificate of GMP Compliance" shall mean a document, signed by an authorized representative of SAD, certifying that the Active Ingredient being delivered to Generex has been manufactured in conformity with cGMPs.

"Confidential Information" shall mean, as the case may be, any and all information, relating to the Active Ingredient, of a confidential nature not known to the public or to the recipient of the information before its disclosure belonging to either Party in written, electronic or any other form. This includes, but is not limited to, Know-How, operational methods,

formulae, samples, Specifications, analytical methods as well as any details of commercial, technical, pharmaceutical, scientific and industrial nature. The terms of this Agreement shall also be deemed Confidential Information. Confidential Information shall not include information, materials, technical data or know-how which: (i) is in a receiving Party's possession at the time of disclosure as evidenced by the receiving Party's written records immediately prior to the time of disclosure; (ii) is in the public domain at the time of disclosure; (iii) becomes part of the public domain by publication or otherwise after disclosure hereunder other than by breach of this Agreement by a receiving Party; (iv) is disclosed to a receiving Party by a third party having the right to disclose such information without any violation of any rights of or obligations to the disclosing Party; or (v) is independently developed by an employee or agent of a receiving Party without knowledge of the disclosing Party's Confidential Information as evidenced by the receiving Party's written records.

"Contract Year" shall mean a twelve (12) month period during the Term, beginning with January 1 and ending on December 31, except that the first "Contract Year" shall be understood to be from November 1, 2009 through December 31, 2009 and the last "Contract Year" for the initial Term shall be understood to run from January 1, 2016 through October 31, 2016..

"Coordinators" shall have the meaning set forth in Article 3 hereof.

"FDA" shall mean the United States Food and Drug Administration or any successor entity thereto.

"FDCA" shall mean the Federal Food, Drug and Cosmetic Act (21 U.S.C. § *et seq.*), as the same may be amended from time to time, together with any rules and regulations promulgated thereunder, and any foreign counterpart.

"Forecast" shall have the meaning set forth in Section 6.1 hereof.

"Force Majeure Event" shall have the meaning set forth in Section 21.1 hereof.

"ICH Guidelines" shall mean the document titled "Q7A - Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" endorsed by the International Conference on Harmonization of Technical Requirements for Registrations of Pharmaceuticals for human use.

"Initial Term" shall have the meaning set forth in Section 12.1 hereof.

"Invention" shall mean information relating to any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.

"Know-How" shall mean all confidential and identified technical and scientific information and data, irrespective of its subject-matter and form, including, but not limited to, processes, formulae, designs and data as well as Inventions and improvements whether patentable or not.

"Minimum Purchase Commitments" shall have the meaning set forth in Section 2.2 hereof.

"Packaging Specifications" shall mean the packaging and labeling specifications for the Active Ingredient attached hereto as Exhibit 3 and made a part hereof, as such specifications may be amended from time to time by mutual agreement of the Parties in accordance with the terms and conditions of the Quality Agreement.

"Product" shall mean Generex's proprietary "Generex Oral-lyn™" product, formulated as a buccal insulin spray device containing a proprietary formulation that includes the Active Ingredient, marketed by Generex (or its licensee(s)) under the registered trademark "GENEREX ORAL-LYN" (or otherwise).

"Production Site" or "Production Sites" shall mean (i) the active pharmaceutical ingredient facility owned by SAD or an Affiliate of SAD (both directly or indirectly under the control of Sanofi-Aventis, SA, the French parent company) located at Industriepark Hoechst, 65926, Frankfurt am Main, Germany, and (ii) such other facilities owned by SAD or an Affiliate of SAD, if any, as the Parties may mutually agree to in writing from time to time.

"Quality Agreement" shall mean the Quality Agreement which the parties shall in good faith negotiate and execute within thirty (30) days after the execution of this Agreement, and which shall be made part hereof.

"Recall" shall have the meaning set forth in Section 13.2(a) hereof.

"Regulatory Change" shall have the meaning set forth in Section 21.2 hereof.

"Renewal Term" shall have the meaning set forth in Section 12.1 hereof.

"Specifications" shall mean the Active Ingredient Specifications and the Packaging Specifications.

"Term" shall have the meaning set forth in Section 12.1 hereof.

"Territory" shall mean, collectively, those territories set forth on Exhibit 1 and Exhibit 1A attached hereto.

"Third Party" shall mean any person or entity other than Generex, SAD and their respective Affiliates.

"Third Party Claims" shall have the meaning set forth in Section 14.1 hereof.

"Third Party Offer" shall be a third party's documented offer for the sale of recombinant human insulin to Generex for commercial production of the Product.

"USA" shall mean the United States of America, including its territories and possessions.

ARTICLE 2
MANUFACTURE, SALE AND PURCHASE OF ACTIVE INGREDIENT

2.1 Generally. Subject to the terms and conditions of this Agreement, SAD shall manufacture and supply to Generex and Generex shall purchase from SAD, the Active Ingredient during the Term of this Agreement for the Territory and as specified in Section 2.2 below.

2.2 Purchase Commitments. Generex shall observe and perform the minimum purchase commitments specified and defined in Exhibit 5 hereto (the "Minimum Purchase Commitments") from the Effective Date through December 31, 2011. SAD shall be the exclusive supplier of Active Ingredient to Generex during such period and thereafter through the Term of this Agreement for those territories listed in Exhibit 1, and as a non-exclusive supplier of Active Ingredient to Generex for those territories listed in Exhibit 1A, unless otherwise agreed to be mutual agreement of the parties or in accordance with the terms of this Agreement.

2.3 Quality Agreement. The Parties shall comply in all respects with their obligations under the Quality Agreement.

2.4 Capacity. Under no circumstances shall SAD be obliged to accept orders or deliver the Active Ingredient in quantities which, in the aggregate, are in **[excess of five hundred (500) kilograms ("Capacity Cap") for a particular Contract Year]***. Starting January 1, 2012 and thereafter, should Generex's rolling forecast(s) (as outlined in Article 6 below), be in **[excess of the Capacity Cap]***, the parties shall discuss such forecast(s) and SAD shall have the right, at its sole discretion, to deny or accept such **[excess}*** forecast(s) or other terms discussed by the parties as set forth above. Should SAD elect not to supply the **[total quantity above the Capacity Cap]***, Generex shall have the right to purchase Active Ingredient from another supplier but only to the extent to obtain the quantities in the forecast not provided by SAD.

2.5 Suppliers. SAD shall have the discretion to determine sources and suppliers for all materials and components used in the manufacture of the Active Ingredient, subject to Article 5 hereof.

2.6 First Right of Refusal.

(a) During the Term, Generex will not accept any Third Party Offer or enter into any arrangement pursuant to which Generex agrees to purchase the Active Ingredient from a Third Party on an exclusive basis for Product to be sold in **[the European Union]*** without first giving SAD a first right to refuse to exclusively supply Active Ingredient to Generex for Product to be sold in **[the European Union]*** on substantially the same terms as the Third Party Offer without material variance.

(b) Upon receipt by Generex of a *bona fide* Third Party Offer that Generex is prepared to accept, Generex shall apprise SAD in writing of the terms of the Third Party Offer.

(c) SAD will have a period of thirty (30) days to from the date of delivery of the Third Party Offer to deliver to Generex an offer in writing (the "SAD Offer") to sell Active Ingredient to Generex on an exclusive basis for Product to be sold in **[the European Union]*** upon the same terms as are contained in the Third Party Offer, which SAD Offer shall be deemed accepted by Generex once received by Generex. Failure to deliver the SAD Offer shall be deemed to be a waiver by SAD indicating declination to exercise the first right of refusal set forth herein. The parties shall execute an amendment to this Agreement which shall reflect the SAD Offer and relevant terms related thereto.

(d) If SAD fails to submit the SAD Offer, Generex will be entitled, for a period of six (6) months after the expiry of the time provided for delivery of the SAD Offer, to execute and deliver contractual documentation formalizing the Third Party Offer with such Third Party on and subject to the terms contained in the Third Party Offer without material variance.

ARTICLE 3
COORDINATORS

Within ten (10) days after the Effective Date, Generex and SAD shall each appoint one or more authorized representatives ("Coordinators") for the exchange of all communications, other than formal notices hereunder, related to the manufacture and supply the Active Ingredient. Each Party shall provide notice to the other Party as to the name and title of the individuals so appointed. Each Party may replace its Coordinators at any time for any reason by providing written notice to the other Party in accordance with Section 24.1 hereof.

ARTICLE 4
PACKAGING

SAD shall procure all packaging materials and components for, and shall package, the Active Ingredient in accordance with the Packaging Specifications as set forth in Exhibit 3 attached hereto. Typical packaging materials and components are described in the Drug Master File in respect of the Active Ingredient and the use thereof is supported by extant stability data.

ARTICLE 5
SPECIFICATION CHANGES

Upon any change in the Active Ingredient Specifications or Packaging Specifications requested by Generex ("Generex Specification Changes"), including the addition of new packaging configurations, Generex shall promptly advise SAD in writing of any requested Generex Specification Changes, and SAD shall promptly advise Generex as to the feasibility of the Generex Specification Changes, and if in SAD's reasonably exercised discretion, the

Generex Specification Changes are found to be commercially reasonable and feasible, SAD will inform Generex of any scheduling and/or price adjustments which may result from the Generex Specification Changes. Prior to implementation of Generex Specification Changes, the Parties shall negotiate in good faith in an attempt to reach agreement on (a) the new Active Ingredient Price for any Active Ingredient which embodies the Generex Specification Changes, (b) any amounts to be reimbursed by Generex to SAD as described in the next sentence of this paragraph, and (c) any other amendments to this Agreement which may be necessitated by the Generex Specification Changes (i.e., an adjustment to the lead time for purchase orders). Generex shall reimburse SAD for the mutually agreed upon reasonable expenses incurred by S AD as a result of the Generex Specification Changes, including, but not limited to, reimbursing SAD for its mutually agreed validation and development costs, capital expenditure costs and costs for any reasonable inventory of packaging components or other materials maintained by SAD for purposes of this Agreement and consistent with any then-current Forecast, and rendered unusable as a result of the Generex Specification Changes. If during the Term, Generex, in accordance with this Article 5, causes the amendment of the Active Ingredient Specifications or Packaging Specifications so as to render obsolete reasonable quantities of the Active Ingredient and/or materials and components used to manufacture and package the Active Ingredient pursuant to this Agreement on hand at SAD, Generex shall purchase from SAD (i) all such obsolete Active Ingredient at the Active Ingredient Prices then in effect, (ii) all work-in-progress of the Active Ingredient at SAD's actual cost thereof, and (iii) at SAD's Acquisition Cost, all such obsolete materials and components obtained by SAD pursuant to its normal procurement policies to manufacture quantities of the Active Ingredient pursuant to Generex' forecasts under Section 6.1. SAD's normal procurement policies for purposes of the preceding sentence of this Article 5 shall be considered to be quantities of materials and components corresponding to the following six (6) months of Generex's forecasted Active Ingredient demand. For greater certainty, the foregoing provisions of this Article 5 shall not apply in respect of any change in the Active Ingredient Specifications or Packaging Specifications made by SAD other than pursuant to a Generex request. SAD shall provide Generex with not less than six (6) months' prior written notice of SAD's implementation of any intended significant change(s) to its manufacturing processes for the Active Ingredient, which might affect the quality of the Active Ingredient ("Change Notice") (e.g. Any change in the Active Ingredient Specifications or Packaging Specifications made by SAD other than pursuant to a Generex request). If a significant change implemented by SAD and Generex provides SAD with demonstrable evidence that the utility (i.e. the conditions of being useful as a pharmaceutical product in connection with the manufacture and performance of the Product) of the Active Ingredient is significantly altered in that there is no similar bioequivalence (to Active Ingredient before the significant change) or similar Product specifications when formulated in the final Product formulation (together, "Utility Loss"), the parties shall exert their best commercial efforts to resolve issues related to the Utility Loss in order to continue operating under this Agreement. If the parties cannot reach agreement and resolution regarding Utility Loss Generex shall have the option to provide sixty (60) days written notice of termination of this Agreement to SAD.

ARTICLE 6
FORECASTS AND ORDERS

6.1 Communication of Forecasts and Purchase Orders by Generex.

Generex shall by the end of each calendar quarter (commencing with the calendar quarter ending December 31, 2009) provide SAD with its non-binding forecast of its Active Ingredient requirements for the succeeding twelve (12) calendar months (each a "Forecast"). Generex shall provide firm and binding Active Ingredient purchase orders for 100% of the Q1 and Q2 amounts in each Forecast, 75% of the Q3 amounts in each Forecast, and 50% of the Q4 amounts in each Forecast. In addition, Generex shall furnish SAD with a non-binding rolling forecast of its Active Ingredient requirements for a subsequent twelve (12) month period (for a total of twenty-four (24) months). Generex shall make its commercially reasonable efforts to provide forecasts at least eighteen (18) months in advance for annual orders that will **[exceed the Capacity Cap]***. Generex shall use its commercially reasonable efforts to provide accurate Forecasts. Forecasts and SAD obligations to supply are subject to **[the Capacity Cap limitations]*** set forth in Section 2.4 above.

Generex shall place with SAD firm purchase orders not later than three (3) months prior to the desired delivery date.

For purchase orders less than or equal to nine (9) kilograms, the minimum quantity in such purchase order shall not be less than three (3) kilograms. For quantities from ten (10) kilograms up to and including one hundred (100) kilograms, the minimum quantity in such purchase order shall not be less than ten (10) kilograms and multiples of ten (10) thereafter. For quantities greater than one hundred (100) kilograms, Generex shall order full batches. Under no circumstances shall SAD be obliged to accept purchase orders or deliver the Active Ingredient pursuant thereto in quantities smaller than the minimum order quantities set out above.

6.2 Confirmation by SAD; Order Confirmation. No later than fifteen (15) business days after receipt of Generex's purchase orders, SAD shall confirm that it can fulfill the monthly quantities specified in such orders, and shall confirm for each relevant portion of such monthly quantities the expected delivery date within the month specified.

6.3 Additional Quantities. If the purchase order quantities are in excess of the Forecast quantities by more than twenty five percent (25%), then SAD shall use commercially reasonable efforts to manufacture and supply the excess quantities up to **[the Capacity Cap]***, with the express understanding that any failure or delay in the delivery of such excess amounts shall not subject SAD to any penalties or other liabilities. Unless otherwise agreed to by SAD before such orders **[exceeding the Capacity Cap]*** were placed, SAD, at its sole discretion, may elect whether or not to manufacture and supply the excess quantities **[above the Capacity Cap]*** for such orders, subject to the terms set out in Section 2.4 above and otherwise set forth in this Agreement.

6.4 Long-Term Planning Forecasts. Within one month after the first day of each Contract Year (Y), Generex will supply SAD with a written four (4) year non-binding rolling forecast reflecting Generex's projected annual Active Ingredient demand for the four (4) Contract Years (Y+1) to (Y+4) following the Contract Year in which such planning forecast is provided to SAD. Such planning forecasts shall represent Generex's most current estimates for planning purposes only, and shall not be considered to be purchase commitments.

ARTICLE 7
REGISTRATION OF THE PRODUCT

7.1 General. Generex shall diligently use good faith commercially reasonable efforts to receive necessary governmental approvals which allow the sale of Product in all territories which comprise the Territory for the Product.

7.2 Cooperation of the Parties. The Parties shall diligently cooperate in good faith to conduct the registration activities required for Product Approval (such Product containing SAD provided Active Ingredient) approval by the regulatory agencies in the countries in the Territory or any countries the Parties contemplate adding to the Territory for the Product containing the Active Ingredient, which costs (i.e.; registration fees) shall be paid solely by Generex. For this purpose, SAD will provide Generex with a letter of reference to its Drug Master File in respect of the Active Ingredient as submitted to the FDA and other relevant governmental regulatory authorities for the Term. In addition, SAD shall provide the specific regulatory agency within a particular territory with a copy of open parts of the Drug Master Files with respect to the Active Ingredient, as submitted to the regulatory agencies of the respective territories comprising the Territory. For clarification, under no circumstance is SAD required to provide any information, data, or other material which SAD, in good faith and at SAD's sole discretion, determines is proprietary or deemed to be the closed parts of the Drug Master File, and by not providing such information, data or other materials, SAD is not in violation of the terms outlined herein and in this Agreement; provided, however, that in the event that Generex is unable to procure Product approval in any territory in the Territory as a consequence of SAD's failure to provide such information, data or other materials related to the Active Ingredient, then this Agreement shall be deemed to be amended by deleting such territory (and, by extension, any Minimum Purchase Commitments in respect of such territory) from Exhibit 1 or Exhibit 1A annexed hereto (such that such territory will no longer be included in the Territory).

ARTICLE 8
DELIVERIES; INSPECTIONS

8.1 Purchase Quantities. SAD will use commercially reasonably efforts to ship the quantities specified in a particular monthly purchase order. Should it be anticipated that there will be a quantity variation (between what is available for shipment and what is outlined in a purchase order) above or below five percent (5%), the parties shall negotiate in good faith on the actual quantity to be shipped. Variations in shipments as outlined herein shall be deemed to be in compliance with such purchase order; provided, however, that Generex shall only be invoiced and required to pay for the quantities of Active Ingredient which SAD actually ships to Generex.

It is understood and accepted by Generex that quantities shipped are subject to the Packaging Specifications set out in Exhibit 3 hereto.

8.2 Active Ingredient Release. No Active Ingredient shall be released to Generex without a Certificate of Analysis and Certificate of GMP Compliance, both of which shall be supplied to Generex by SAD. SAD shall conduct such quality assurance testing for the Active Ingredient as is required by the Specifications, cGMPs and the Quality Agreement. SAD shall conduct in parallel on-going stability studies of the Active Ingredients.

8.3 Delivery Terms. Shipment of the Active Ingredient will be to one location as designated by Generex. Generex will select and pay the carrier to be used. The Active Ingredient will be shipped with the requisite Certificates of Analysis and Certificate of cGMP Compliance FCA Production Site (Incoterms 2000), freight class, Class 70 (Class of Commodity for Food and Pharmaceutical Compound). Loading of the Active Ingredient shall be performed at no cost by SAD, but under the responsibility and liability of Generex. All shipments of the Active Ingredient to Generex shall be made via such carrier(s) as Generex may direct. Title and risk of loss shall pass to Generex upon delivery to the carrier. Freight charges shall be billed ship collect.

8.4 Shipping; Dating and Customs Costs. SAD shall make commercially reasonable efforts to cause Active Ingredient delivered hereunder to have eighteen (18) months until expiration, but in any event, SAD shall deliver Active Ingredient hereunder with at least twelve (12) months until expiration. For clarity, costs for the shipment of Active Ingredient from the Production Site and all customs tariffs and duties shall be for the account of Generex.

8.5 Inconsistencies. In the event of any inconsistencies between the terms of this Agreement and any purchase order issued by Generex hereunder or any acceptance thereof by SAD, the terms of this Agreement shall govern.

8.6 Inspections by Generex. Upon reasonable prior written notice, the single Generex designated agent which is reasonably agreed to by SAD, together with up to two (2) Generex employees, shall have the right to inspect those portions of the manufacturing, storage and warehouse facilities of a Production Site where Active Ingredient is being manufactured or stored, during regular business hours, to verify compliance with the terms and provisions of this Agreement or for insurance inspection purposes. Unless for reasonable cause, Generex agrees to not inspect a Production Site more often than one (1) time in three (3) calendar years.

8.7 Governmental Inspections. If SAD is notified that the Active Ingredient or the Production Site will be subject to an inspection, related to the Active Ingredient, by any governmental authority for a particular territory listed in Exhibit 1 or 1A, SAD shall promptly inform Generex of such inspection and shall cooperate with and allow such inspection to the extent required by applicable laws. Generex shall not have the right to be present at any meetings or events related to such inspection. Subject to being excluded due to restrictions under confidentiality obligations of SAD to Third Parties, and to SAD's determination that particular information and/or documentation is confidential in nature, SAD shall provide information related to inspection outcomes to Generex resulting from such inspection to the extent relevant to

the Active Ingredient. SAD will promptly inform Generex whether any Form FDA 483 or warning letters or citations are issued to SAD (by the FDA or any other governmental authority for a particular territory listed in Exhibit 1 or Exhibit 1A) which are related to or impact the supply of the Active Ingredient.

ARTICLE 9
PRICE; PRICE ADJUSTMENTS; PAYMENT TERMS

9.1 Price. The per-kilogram price(s) payable by Generex for all quantities of the Active Ingredient ordered hereunder (the "Active Ingredient Price(s)") shall be as specified in the pricing schedule in Exhibit 2 hereto; as such prices may be revised from time to time pursuant to Article 5 and Article 9.

9.2 Price Adjustments. The Active Ingredient Price through December 31, 2012 shall be as specified in the pricing schedule in Exhibit 2 attached hereto. Subject to Article 5 hereof, the Active Ingredient Price(s) listed in Exhibit 2 for each Contract Year thereafter shall be equal to the Active Ingredient Price(s) in effect at the end of the immediately preceding Contract Year, increased (or decreased, as the case may be) by a percentage equal to fifty percent (50%) of the percentage increase (or the decrease, as the case may be) in the Producer Price Index of the Federal Republic of Germany (the "PPI") over the course of the immediately preceding Contract Year, calculated as the average of the twelve (12) monthly PPI data reports of the Federal Statistical Office Germany during the immediately preceding Contract Year.

9.3 Payment Terms. SAD shall invoice Generex for all quantities of the Active Ingredient purchased hereunder concurrently with SAD's shipment thereof to Generex. Subject to Section 13.1, and Section 8.3, all amounts properly invoiced by SAD hereunder shall be due and payable **[sixty (60)]*** days from the date of such invoice, except that for the first two Contract Years (for the Minimum Purchase Commitments only and payment thereof in 2009 and 2010), Generex shall submit payment within **[one hundred and twenty (120)]*** days from the date of invoice. SAD shall deliver invoices to Generex on the date the invoice is issued. Payment may be made by Generex's corporate check or by wire transfer of funds to such account as SAD may designate. Orders, invoices and payments under this Agreement shall be made in Euros. Invoices shall reflect the actual quantities shipped and Generex shall be responsible for payment for such actual quantities shipped in accordance with this Agreement and the Packaging Specifications set out in Exhibit 3 hereto.

ARTICLE 10
SAD'S REPRESENTATIONS, WARRANTIES AND COVENANTS

SAD represents, warrants and covenants to Generex as follows:

10.1 Active Ingredient. The Active Ingredient, at the time of sale and shipment to Generex by SAD, (a) will conform to the Specifications, as then in effect, (b) will have dating until re-evaluation of not less than that which is set forth in Section 8.4 above, (c) will have been manufactured in all material respects in accordance with cGMP in effect at the time of

manufacture, (d) will not be adulterated or mis-branded within the meaning of the FDCA, (e) will not have been manufactured, sold or shipped in violation of any applicable laws in any material respect, (f) will be conveyed with good title, free and clear of all security interests, liens or encumbrances, and (g) as may be appropriate or applicable, will have been approved by any and all requisite governmental and regulatory authorities.

10.2 Manufacturing Standards. SAD shall manufacture the Active Ingredient in accordance with (i) the Specifications, (ii) then-current cGMPs, and (iii) applicable ICH Guidelines.

10.3 Compliance with Applicable Laws. SAD shall fully comply with all applicable federal, state and local laws in the Territory, as they relate to the manufacture or sale of pharmaceutical products, in performing the services contemplated hereunder.

10.4 Qualified Personnel. SAD shall engage and employ only professionally qualified personnel to perform the services contemplated hereunder, and will not knowingly utilize any individual, in any material capacity, who has been debarred under FDCA 21 USC 335a or who is subject to a conviction described in FDCA 21 USC 331.

10.5 SAD represents and warrant to Generex that the Facility is wholly-owned by an affiliate of SAD and that such affiliate and SAD are wholly owned, directly or indirectly, by sanofi-aventis SA.

ARTICLE 11
GENERAL REPRESENTATIONS AND WARRANTIES

Each Party represents and warrants to the other as follows:

11.1 Power and Authorization. It has all requisite power and authority (corporate and otherwise) to enter into this Agreement and has duly authorized by all necessary action the execution and delivery hereof by the officer or individual whose name is signed on its behalf below.

11.2 No Conflict. Its execution and delivery of this Agreement and the performance of its obligations hereunder do not and will not conflict with or result in a breach of or a default under its organizational instruments or any other agreement, instrument, order, law or regulation applicable to it or by which it may be bound.

11.3 Enforceability. This Agreement has been duly and validly executed and delivered by it and constitutes its valid and legally binding obligation, enforceable in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency or other laws of general application relating to or affecting the enforcement of creditors' rights and except as enforcement is subject to general equitable principles.

11.4 Debarment. As of the Effective Date, neither party has been debarred under FDCA 21 USC 335a, and to the best of its knowledge, is not subject to pending debarment under FDCA 21 USC 335a.

ARTICLE 12
TERM; TERMINATION

12.1 Term. Unless sooner terminated pursuant to the terms hereof, the term of this Agreement shall commence on the Effective Date and shall expire on October 31, 2016 (the "Initial Term"). Upon the expiration of the Initial Term, this Agreement shall automatically and continually renew for successive three (3) year terms (each, a "Renewal Term", and the Initial Term and all Renewal Terms being collectively referred to as the "Term") unless either Party notifies the other in writing at least twenty-four (24) months prior to the end of the Initial Term or any Renewal Term, as the case may be, of its intent that this Agreement shall expire without further renewal.

12.2 Third Party Distribution. In the event that Generex (a) executes and delivers an agreement with a Third Party pursuant to which the Third Party agrees to distribute the Product in one or more territories listed in Exhibit 1 (each a "Third Party Distribution Jurisdiction"), and (b) the business of such Third Party includes the manufacture of recombinant human insulin, then, upon not less than thirty (30) days' prior written notice by Generex to SAD, this Agreement shall be deemed to be amended by deleting the Third Party Distribution Jurisdiction (and, by extension, any Minimum Purchase Commitments in respect of such Third Party Distribution Jurisdiction) from Exhibit 1 annexed hereto (such that the Third Party Distribution Jurisdiction will no longer be included in the Territory for Exhibit 1), and at the sole option of SAD, to move such Third Party Distribution Jurisdiction to Exhibit 1A or remove from the Agreement in its entirety.

12.3 Termination by Generex for Utility Loss. Generex shall be entitled to terminate this Agreement pursuant to and in accordance with Article 5 in the event of a Utility Loss. In the event of a termination by Generex in accordance with this Section 12.3 and Article 5, Generex's then-current obligations under this Agreement shall remain until fully satisfied, including the payment of amounts due to SAD for Active Ingredient or otherwise, which are not related to Utility Loss.

12.4 Termination For Low Volume. This Agreement may be terminated by SAD in its sole discretion after December 31, 2011, upon not less than twelve (12) months' prior written notice in the event that the forecasted purchase volumes of Generex for Active Ingredient pursuant to Section 6.1 hereof for the next two (2) calendar quarters (Q+1 though Q+2) is less than ten (10) kilograms ("Low Volume"). The parties acknowledge and agree that they shall have good faith discussions regarding Low Volume issues prior to any SAD termination in accordance with this Section 12.4, but that SAD retains the right to terminate as set forth above. Within six (6) months of Generex receiving SAD's written termination notice in accordance with this Section 12.4, Generex shall have the option to request, and the parties shall then have, a

second good faith discussion regarding Low Volume, subject to SAD having the ultimate right to have the termination become effective as set out herein.

12.5 Termination Upon Delay of Commercialization. Should the project of commercializing the Product be delayed beyond December 31, 2011 in any particular territory in the Territory, then, at SAD's discretion and upon not less than thirty (30) days' prior written notice by SAD to Generex, this Agreement shall be deemed to be amended by deleting such territory (and, by extension, any Minimum Purchase Commitments in respect of such territory) from Exhibit 1 or Exhibit 1A annexed hereto (such that such territory will no longer be included in the Territory).

12.6 Termination For Failure of Bridging Study or In-Vitro Physio-Chemical Characterizations (each a "Study"). Generex acknowledges and agrees that Generex is obligated to perform a Study if required by a regulatory authority in any territory as listed in Exhibit 1 or 1A at Generex's sole cost and expense. Either party shall have the right to terminate this Agreement without further obligation if (a) a Study is conducted involving not less than fifty (50) patients and that Study does not demonstrate non-inferiority of Product utilizing the Active Ingredient supplied by SAD, or (b) any in-vitro physio-chemical characterizations (as outlined in Exhibit 6) carried out on the Active Ingredient supplied by SAD cannot be used to establish suitable equivalence to the recombinant human insulin product supplied by N.V. Organon and utilized in the Product prior to the date hereof. Generex shall promptly communicate the results of any completed Study and/or characterizations to SAD. SAD shall have the right, at its sole expense, to audit and receive for review any documentation or information related to a Study and/or characterizations in order to verify that the same were conducted in accordance with industry practice. The termination right under this Section 12.6 must be exercised within sixty (60) days of the date the results of a Study and/or characterizations are available to Generex.

12.7 Termination by Mutual Agreement. The Parties may terminate this Agreement at any time by mutual written agreement.

12.8 Termination Upon Breach. Either Party may terminate this Agreement upon not less than ninety (90) days' prior written notice to the other Party upon the material breach or default by the other Party of any of its representations, warranties, covenants or agreements (provided, however, that such notice period shall be extended by such additional period as the breaching Party may request, not exceeding six (6) months, upon the breaching Party's written certification that (i) such breach is not reasonably capable of being cured within such ninety (90) day period, and (ii) it has commenced and is diligently pursuing efforts to cure such breach). Upon the expiration of such notice period, this Agreement shall terminate without the need for further action by either Party; provided, however, that if the breach upon which such notice of termination is based shall have been fully cured to the reasonable satisfaction of the non-breaching Party within such notice period, then such notice of termination shall be deemed rescinded, and this Agreement shall be deemed reinstated and in full force and effect. Such right of termination shall be in addition to such other rights and remedies specified in this Agreement and as provided by law. For greater certainty, any breach or default (material or otherwise) by a Party under any other agreement between the Parties (other than the Quality Agreement) shall not entitle the other Party to terminate this Agreement.

12.9 Rights and Duties Upon Termination.

(a) Unless otherwise mutually agreed by the Parties, SAD shall manufacture and ship, and Generex shall purchase in accordance with the provisions hereof, all quantities of Active Ingredient ordered by Generex hereunder prior to the date of expiration or termination

(b) Upon the expiration or termination of this Agreement (other than termination by Generex pursuant to Section 12.3 or Section 12.8 hereof), Generex shall, if so requested by SAD, purchase (i) all materials and components acquired by SAD hereunder to manufacture the Active Ingredient in accordance with the then-current Forecast or Minimum Purchase Commitments, at SAD's Acquisition Cost thereof, (ii) all work-in-progress of the Active Ingredient in respect of the then-current Forecast or Minimum Purchase Commitments at SAD's actual cost thereof, and (iii) all finished Active Ingredient inventory in respect of the then-current Forecast or Minimum Purchase Commitments, then in SAD's possession at the then-current Active Ingredient Price hereunder. In addition, in such case Generex shall pay SAD for any uncancellable commitments made by SAD for materials and components made by SAD hereunder in respect of the then-current Forecast or Minimum Purchase Commitments. Notwithstanding anything to the contrary in the preceding two sentences, the foregoing purchase and payment obligations of Generex shall be limited solely to materials and components obtained as to the time periods for the types of materials and components provided in Section 5, and Active Ingredient quantities manufactured as to which Generex' forecasts under Section 6.1 hereof constitute a firm commitment.

ARTICLE 13
CLAIMS; RECALLS

13.1 Claims. Generex may reject any quantity of the Active Ingredient which fails to conform to any applicable purchase order, warranty, or Specifications upon written notice to SAD describing such nonconformity given within thirty (30) days after Generex's receipt thereof (or, in the case of any defects not reasonably susceptible of discovery upon receipt of such goods, within thirty (30) days after discovery thereof by Generex). SAD shall have no liability to Generex with respect to any such nonconformity which the Parties agree (or, absent such agreement, which a mutually acceptable independent laboratory or consultant determines) (i) was caused by information supplied by Generex or due to a fault in materials supplied by Generex, (ii) was otherwise caused by Generex or its agents, or (iii) was caused after delivery thereof to the carrier at the point of origin. In all other cases, SAD shall promptly credit Generex's account for SAD's invoice price to Generex of such nonconforming Active Ingredient. Additionally, if Generex shall have previously paid for such nonconforming Active Ingredient, SAD shall promptly, at Generex's election, either (a) refund the invoice price thereof (b) offset the amount thereof against other amounts then due SAD hereunder or (c) replace such nonconforming Active Ingredient with conforming Active Ingredient at no additional cost to Generex. The foregoing remedy constitutes the exclusive remedy against SAD and the entire liability of SAD in connection with the rejected shipment. . The fees and expenses of any independent laboratory

or consultant engaged by the Parties for purposes of this section shall be paid by the Party which is determined to bear responsibility for the nonconformity in question.

13.2 Recalls.

(a) Notices. Each Party shall notify the other of any information, whether received directly or indirectly, which might affect the marketability, safety or effectiveness of Product which was manufactured using Active Ingredient supplied by SAD hereunder and/or which might result in the Recall or seizure of the Product which was manufactured using Active Ingredient supplied by SAD hereunder. For purposes of this Agreement, a "Recall" shall mean any action: (i) by either Party to recover title to or possession of quantities of the Product which was manufactured using Active Ingredient supplied by SAD hereunder sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of such Product which was manufactured using Active Ingredient supplied by SAD hereunder from the market) or (ii) by any regulatory authorities to detain or destroy any of such Product which was manufactured using Active Ingredient supplied by SAD hereunder. "Recall" shall also include the election by either Party to refrain from selling or shipping quantities of such Product which was manufactured using Active Ingredient supplied by SAD hereunder to Third Parties that would have been subject to a Recall if sold or shipped.

(b) Discretion. Generex shall institute a Recall of the Product as a consequence of any defect that Generex deems sufficiently serious. Generex shall consult with SAD regarding any Recall of Product which was manufactured using Active Ingredient supplied by SAD hereunder; provided, however, that Generex shall retain sole discretion whether to institute a Recall. SAD shall provide a rapid initial response and a full report with respect thereto within thirty (30) calendar days of such notification.

(c) Responsibilities. SAD shall have no liability to Generex with respect to any Recall which the Parties agree (or, absent such agreement, which a mutually acceptable independent laboratory or consultant determines) (i) was caused by information or materials supplied by Generex, (ii) was otherwise caused by Generex or its agents, (iii) was caused by factors occurring after delivery of the Active Ingredient to the carrier at the Production Site, or (iv) did not result from a breach of SAD's warranties provided under Article 10 hereof. In addition, Generex shall reimburse SAD for all reasonable out-of-pocket Third Party costs and expenses incurred and not recovered by SAD directly resulting from such Recall (subject to the limitations set forth in Section 16.2 hereof). For all Recalls which result from a breach of SAD's warranties provided under Article 10 hereof, unless SAD does not have liability pursuant to this Section 13.2(c), SAD shall: (x) promptly credit Generex's account for SAD's invoice price to Generex of the Active Ingredient used in such Recalled Product; if Generex shall have previously paid for such Active Ingredient, SAD shall promptly, at Generex' election, either (A) refund the invoice price thereof, or (B) offset the amount thereof against other amounts then due SAD hereunder, or (C) replace such Active Ingredient at no additional cost to Generex (y) reimburse Generex, subject to the limitation set out in subsection 13.2(e) below, for all reasonable out-of-pocket Third Party costs and expenses incurred and not recovered by Generex directly resulting from such Recall (subject to the limitations set forth in Section 16 hereof).

(d) Independent Laboratory Costs. The fees and expenses of any independent laboratory or consultant engaged by the Parties for purposes of this Section 13.2 shall be paid by the Party which is determined to bear responsibility for the Recall in question.

(e) Limitation. Notwithstanding any other provision of this Agreement, the liability of SAD to reimburse Generex for Third Party costs and expenses pursuant to Section 13.2(c)(y) hereof related to any Recall shall not exceed **[five hundred thousand]*** ($**[500,000]***) dollars plus fifty percent (50%) remaining liability up to **[one million two hundred and fifty thousand]*** dollars ($**[1,250,000]***) in respect of each such Recall. For clarification, SAD shall have a maximum per recall liability of **[eight hundred and seventy five thousand]*** ($**[875,000]***) dollars. The Parties shall, to the extent possible, meet to review, in advance, actions and budgets for any Recall for which SAD shall have financial responsibility to Generex pursuant to this Section 13.2.

13.3 Disposition of Nonconforming or Recalled Product. Generex shall not dispose of any damaged, nonconforming or Recalled Product as to which it intends to assert a claim against SAD without SAD's written authorization to do so. Alternatively, SAD may instruct Generex to return such Product to SAD. SAD shall bear the cost of disposition (as well as all applicable shipping costs) with respect to any damaged, nonconforming or Recalled Product as to which it bears responsibility under Section 13.1 or 13.2 hereof.

ARTICLE 14
INDEMNIFICATION

14.1 By Generex. Generex shall defend, indemnify and hold harmless SAD, its Affiliates and their respective officers, directors, shareholders, employees, licensees, agents, successors and assigns from and against any and all claims, demands, damages, judgments, settlements and awards made or asserted by Third Parties (collectively, "Third Party Claims") (including, without limitation, those associated with a Recall) which any of them may incur or become subject to arising out of or resulting from (a) Generex's use, handling, distribution, marketing or sale of the Active Ingredient (subject to Section 14.2 hereof) or the Product, (b) the breach by Generex of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement (c) any claim that the manufacture, use or sale of the Product (which for purposes of this section, includes Active Ingredient) infringes a patent or any other proprietary rights, or (d) any other claim that arises from and is related to the Product; provided, however, that such obligation to indemnify shall not extend to any Third Party Claim to the extent they arise out of or resulting from any negligence, recklessness or wrongful conduct by SAD or the breach by SAD of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement. It is understood that for purposes of this Section 14.1, and as related to Third Party Claims as defined above, "Generex" shall include Generex Affiliates.

14.2 By SAD. SAD shall defend, indemnify and hold harmless Generex, its Affiliates and their respective officers, directors, shareholders, employees, licensees, agents, successors and assigns from and against any and all Third Party Claims which any of them may incur or become subject to arising out of or resulting from (a) SAD's negligent acts or omissions or

willful misconduct in connection with the performance of the services contemplated by this Agreement, (b) the breach by SAD of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement, or (c) any claim that SAD's manufacture, use or sale of the Active Ingredient alone infringes a patent or any other proprietary rights; provided, however, that such obligation to indemnify shall not extend to any Third Party Claim to the extent they arise out of or resulting from any negligence, recklessness or wrongful conduct by Generex or the breach by Generex of any of its representations, warranties, covenants, obligations, agreements or duties under this Agreement.

14.3 Procedure. Promptly after learning of the occurrence of any event which may give rise to its rights under the provisions of this Article 14, each indemnitee hereunder shall give written notice of such matter to the indemnitor. The indemnitee shall cooperate with the indemnitor in the negotiation, compromise and defense of any such matter. The indemnitor shall be in charge of and control such negotiations, compromise and defense and shall select and manage counsel with respect thereto, provided that the indemnitor shall promptly notify the indemnitee of all developments in the matter, In no event shall the indemnitee compromise or settle any such matter without the prior written consent of the indemnitor, who shall not be bound by any such compromise or settlement absent its prior written consent, which consent shall not be unreasonably withheld or delayed.

ARTICLE 15
INSURANCE

Each Party represents that it has and shall maintain during the Term hereof, as well as after the expiration or termination of this Agreement, sufficient insurance or an appropriate program of self insurance, and in particular products liability insurance, with appropriate policy limits to cover all risks associated with the performance of its obligations under this Agreement. Each Party agrees to provide upon request copies of the relevant certificate(s) of insurance.

ARTICLE 16
LIMITATION OF LIABILITY

16.1 DISCLAIMER OF WARRANTIES. THE WARRANTIES GIVEN BY SAD HEREUNDER ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES ARE HEREBY DISCLAIMED AND EXCLUDED BY SAD PARTY.

16.2 DAMAGES. SAD SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING, WITHOUT LIMITATION, LOST PROFITS AND LOSS OF GOODWILL) ARISING FROM ANY BREACH OR ALLEGED BREACH OF THIS AGREEMENT (EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES).

16.3 Remedies. SAD's sole obligations, and Generex's sole and exclusive remedies, for any breach by SAD of this Agreement related to nonconforming Active Ingredient or Recalled Product shall be as set forth in Sections 13.1 and 13.2 hereof, respectively.

16.4 LIMITATION. EXCEPT FOR SAD'S INDEMNIFICATION OBLIGATIONS FOR THIRD PARTY CLAIMS, IN NO EVENT SHALL SAD'S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS OR LOSSES ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED THE HIGHEST AGGREGATE AMOUNTS PAID TO SAD HEREUNDER DURING ANY TWELVE (12) MONTH PERIOD PRECEDING THE EVENT GIVING RISE TO LIABILITY, BUT IN NO EVENT SHALL SAD'S LIABILITY EXCEED FIVE MILLION ($5,000,000.00) DOLLARS, IN THE AGGREGATE OVER THE ENTIRE TERM.

ARTICLE 17
CONFIDENTIALITY

17.1 Treatment of Confidential Information. Except as otherwise provided in this Article 17, during the Term and for a period of ten (10) years thereafter:

(i) SAD will retain in confidence and use only for the purposes contemplated hereby any Confidential Information disclosed to it by or on behalf of Generex in connection with the performance of this Agreement; and

(ii) Generex will retain in confidence and use only for the purposes contemplated hereby any Confidential Information disclosed to it by or on behalf of SAD in connection with the performance of this Agreement.

17.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, each Party may disclose Confidential Information to its Affiliates, sublicensees, consultants, outside contractors, clinical investigators or other Third Parties on condition that such entities or persons agree (a) to keep the Confidential Information confidential for the same time periods and to the same extent as each Party is required to keep the Confidential Information confidential and (b) to use the Confidential Information only for such purposes as such Party is entitled to use the Confidential Information. Each Party or its Affiliates or sublicensees may disclose such Confidential Information to government or other regulatory authorities to the extent that such disclosure (i) is reasonably necessary to obtain patents or authorizations to conduct clinical trials with and to market commercially the Product, provided such Party is otherwise entitled to engage in such activities under this Agreement or (ii) is otherwise legally required.

ARTICLE 18
OWNERSHIP OF PROPERTY

18.1 Ownership of Rights. Each Party shall exclusively own and retain all right, title and interest in and to (i) all intellectual property rights, information, documents and tangible and

intangible materials owned by it as of the Effective Date, and (ii) all Inventions which are conceived, reduced to practice, or created by such Party and/or its Affiliates or agents (including without limitation Inventions based upon any background or preexisting technology of such Party) and which do not include any intellectual property rights of the other Party from and after the Effective Date. Each Party shall be solely responsible for the conduct and costs of filing, prosecution and maintenance of patents and patent applications on its own intellectual property rights, including without limitation its Inventions.

18.2 Trademarks. Generex shall retain all right, title and interest arising under the U.S. Trademark Act and all other applicable laws in the trademarks of Generex that may be adopted with respect to the Product.

ARTICLE 19

Intentionally omitted.

ARTICLE 20
COOPERATION WITH GOVERNMENTAL REQUIREMENTS

The Parties shall cooperate with one another as may be reasonably necessary or appropriate to satisfy all governmental requirements and obtain all needed permits, approvals and licenses with respect to the manufacture and supply of the Active Ingredient. Such cooperation shall include, without limitation, communicating with regulatory authorities and making available as promptly as practicable all information, documents and other materials which result from the performance by SAD of its services hereunder which Generex is required to submit or which Generex may otherwise reasonably request in connection with governmental filings relating to the Active Ingredient. The costs and expenses of such cooperation, if applicable, shall be subject to the Parties' mutual agreement. Notwithstanding the foregoing, it shall be the responsibility of (i) Generex to obtain and maintain all such permits, approvals and licenses which are specific to the Active Ingredient or the Product, and (ii) SAD to obtain and maintain all such permits, approvals and licenses which are generally required for the Production Site and to maintain the Drug Master File in respect of the Active Ingredient.

ARTICLE 21
FORCE MAJEURE

21.1 Effects of Force Majeure. Neither Party shall be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement (other than the payment of money owed hereunder) to the extent that such failure or delay results from any cause beyond its reasonable control, including, without limitation, fire, flood, natural disaster, explosion, war, strike, labor unrest, riot, embargo, acts or omissions of carriers, or act of God (each, a "Force Majeure Event"). Such excuse shall continue as long as the Force Majeure Event continues, following which such Party shall promptly resume performance hereunder.

21.2 Effects of Regulatory Changes. Neither Party shall be held responsible or liable for failure or delay in fulfilling or performing any of its obligations under this Agreement to the extent that such failure or delay results from good faith efforts to comply with the enactment or revision of any law, rule, regulation or regulatory advisory opinion or order applicable to the manufacturing, marketing, sale, reimbursement and/or pricing of the Product (a "Regulatory Change"). Such excuse shall continue as long as performance is prevented by the affected Party's good faith efforts to comply with such Regulatory Change, following which such Party shall promptly resume performance hereunder.

21.3 Notice. The Party affected by a Force Majeure Event or a Regulatory Change shall notify the other Party thereof as promptly as practicable after its occurrence. Such notice shall describe the nature of such Force Majeure Event or Regulatory Change and the extent and expected duration of the affected Party's inability to fully perform its obligations hereunder. The affected Party shall use due diligence, where practicable, to minimize the effects of or end any such event so as to facilitate the resumption of full performance hereunder and shall notify the other Party when it is again fully able to perform such obligations.

ARTICLE 22
INDEPENDENT CONTRACTORS

The relationship between Generex and SAD is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between Generex and SAD. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

ARTICLE 23
FURTHER ACTIONS

General. The Parties agree to execute such additional documents and to perform all such other and further acts as may be necessary or desirable to carry out the purposes and intents of this Agreement.

ARTICLE 24
MISCELLANEOUS

24.1 General Notices. Except as otherwise provided in Section 24.2 hereof, all notices, requests, instructions, consents and other communications to be given pursuant to this Agreement shall be in writing and shall be deemed received (i) on the same day if delivered in person, by same-day courier or by facsimile transmission, (ii) on the next day if delivered by overnight mail or courier, or (iii) on the date indicated on the return receipt, or if there is no such receipt, on the third calendar day (excluding Sundays) if delivered by certified or registered mail, postage prepaid, to the Party for whom intended to the following addresses:

If to Generex:

GENEREX BIOTECHNOLOGY CORPORATION
33 Harbour Square, Suite 202,
Toronto, Ontario, Canada M5J 2G2
Attention: *Rose C. Perri,*
Chief Operating Officer
FAX: 1-416-364-9363

If to SAD:

SANOFI-AVENTIS DEUTSCHLAND GMBH
Industriepark Hoechst, 65926
Frankfurt am Main, Germany

Each Party may by written notice given to the other in accordance with this Agreement change the address to which notices to such Party are to be delivered.

24.2 Special Notices. Each Party shall notify the other by telephone as soon as practicable (with written confirmation within three business days) upon its receipt of any technical complaint or notice of adverse reaction; provided, however, that notification of serious, new or unexpected experiences reported with increased frequency shall be made immediately (but in any event not more than thirty-six (36) hours after the notifying Party learns of such experiences). All such notices shall be directed to the Parties at the addresses set forth in Section 24.1 to the attention of the following personnel:

If to Generex:

Technical complaints: George Markus, Vice-President, Regulatory Affairs

Adverse reactions: George Markus, Vice-President, Regulatory Affairs

If to SAD:

Technical complaints: Site Quality Manager

Adverse reactions: Site Quality Manager

24.3 Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, whether written or oral, between them with respect to the subject matter hereof. Each Party has executed this Agreement without reliance upon any promise, representation or warranty other than those expressly set forth herein.

24.4 Amendment. No amendment of this Agreement shall be effective unless embodied in a written instrument executed by both of the Parties.

24.5 Waiver of Breach. The failure of either Party at any time to enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any provisions hereof or the right of any Party to thereafter enforce each and every provision of this Agreement. No waiver of any breach of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the Party against whom or which enforcement of such waiver is sought; and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.

24.6 Subcontracting. Neither Party shall subcontract any of its obligations under this Agreement; provided, however, that (i) either party may subcontract to a Third Party any of its obligations under this Agreement with the prior written approval of the other Party, such approval not to be unreasonably withheld, and (ii) SAD may subcontract any services to an Affiliate, or otherwise if permitted in the Specifications or Packaging Specifications, including without limitation the supply of materials and components, or pursuant to Section 24.7 hereof.

24.7 Assignment; Requirement to Assign to Successor to Business. Neither Party may assign its rights under this Agreement in whole or in part without the prior written approval of the other Party (such approval not to be unreasonably withheld or delayed). Any such attempted assignment without such prior written consent shall be void and ineffective. Should SAD consent to an assignment by Generex to another party, Generex shall assign its rights and delegate its duties under this Agreement in whole or in part to such party, and shall ensure that such party (A) undertakes in writing with SAD to observe and perform the obligations of Generex hereunder and under the Quality Agreement, (B) has adequate financial resources (equal or superior to Generex's financial resources as of the date of the assignment) to perform Generex's financial obligations hereunder, and (C) meets with SAD to review the future of manufacturing for the Active Ingredient. Notwithstanding the foregoing, SAD may assign this Agreement to an Affiliate.

24.8 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of New York without regard to its conflicts of laws principles.

24.9 Severability. All of the provisions of this Agreement are intended to be distinct and severable. If any provision of this Agreement is or is declared to be invalid or unenforceable in any jurisdiction, it shall be ineffective in such jurisdiction only to the extent of such invalidity or unenforceability. Such invalidity or unenforceability shall not affect either the balance of such provision, to the extent it is not invalid or unenforceable, or the remaining provisions hereof, nor render invalid or unenforceable such provision in any other jurisdiction.

24.10 Publicity. Nothing in this Agreement shall be deemed to give either Party any rights to use the other Party's trademarks or trade names without the other Party's prior specific, written consent. Neither party will issue any press release or otherwise make any public statement, advertisement or disclosure with respect to this Agreement or Products which contain SAD Active Ingredient or the transactions contemplated hereby without the prior written consent of the other Party, which shall not be unreasonably withheld; provided, however, if, in the opinion of the disclosing Party's legal counsel, such announcement is necessary to comply with applicable law, either Party shall be entitled to make a public announcement of this Agreement

and/or file a Form 8-K Current Report with the Securities and Exchange Commission, subject to the prior review and approval of such press release and/or Form 8-K by the other Party, which approval will not be unreasonably withheld or delayed and provided to the extent practicable the other Party has received at least three (3) business days notice. Mutually agreed upon redacted versions of this Agreement may be exhibits to the Form 8-K Current Report. In addition, Generex will be entitled to make reference to this Agreement in reports filed with the Securities and Exchange Commission, after providing SAD advance and a reasonable opportunity to review and comment thereon.

24.11 Survival. The provisions of 12.9 (Rights and Duties Upon Termination), Article 13 (Claims; Recalls), Article 14 (Indemnification), Article 15 (Insurance), Article 16 (Limitation of Liability), Article 17 (Confidentiality), Article 18 (Ownership of Property), Article 20 (Cooperation with Governmental Requirements), Section 24.8 (Governing Law), Section 24.10 (Publicity) and Section 24.11 (Survival) shall survive the expiration or termination of this Agreement.

24.12 Headings. The headings of articles and sections have been included for convenience only and shall not be considered in interpreting this Agreement.

24.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. This Agreement may be executed and delivered via electronic facsimile transmission with the same force and effect as if it were executed and delivered by the Parties simultaneously in the presence of one another.

24.14 Execution. At the time of execution of this Agreement, the Parties shall cause their authorized officers to execute two original copies of this Agreement, one copy of which shall be maintained by each Party at that Party's offices. Each Party represents that the person who executes this Agreement is authorized and empowered to obligate and bind his or her Party under this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the day and year first above written.

GENEREX BIOTECHNOLOGY CORPORATION

By: /s/ Anna E. Gluskin

Name: Anna E. Gluskin

Title: President, Chief Executive Officer

By: /s/ Rose C. Perri

Name: Rose C. Perri

Title: Chief Operating Officer, Chief Financial Officer

SANOFI-AVENTIS DEUTSCHLAND GMBH

By: /s/ M. Braun

Name: M. Braun

Title: Vice President

SANOFI-AVENTIS DEUTSCHLAND GMBH

By: /s/ Klaus Menken

Name: Dr. Klaus Menken

Title: CFO Germany

Exhibit 1

TERRITORIES: EXCLUSIVE

Territories where Generex will register Generex Oral-lyn
with the Active Ingredient to be supplied by SAD on an exclusive basis

[REMAINDER OF PAGE REDACTED]*

[Abu Dhabi
Albania
Algeria
Armenia
Bahrain
Brazil
Canada
Costa Rica
Ecuador
Egypt
Georgia
Ghana/Togo
Iran
Iraq
Jordan
Kosovo
Kuwait
Lebanon
Libya
Macedonia
Madagascar
Mexico
Morocco
Oman
Palestine
Qatar
Saudi Arabia
Syria
Trinidad/Tobago
Tunisia
Turkey
UAE
United States of America
Yemen]*

Exhibit 1A

TERRITORIES: NON-EXCLUSIVE

Territories where Generex will register Generex Oral-lyn
with the Active Ingredient to be supplied by SAD on a non-exclusive basis

[REMAINDER OF PAGE REDACTED]*

[India
Indonesia
Malaysia
Pakistan
Philippines
Singapore
Thailand
Vietnam]*

Exhibit 2

ACTIVE INGREDIENT PRICES

The Active Ingredient Prices payable by Generex to SAD through December 31, 2012 will be as follows:

a.	For the first **[100]*** kg:	**[79]*** € per gram;
b.	for the succeeding **[150]*** kg:	**[75]*** € per gram; and
c.	thereafter:	**[73]*** € per gram.

Such pricing (in Euros) is subject to adjustment pursuant to Articles 5 and 9 of the Agreement. In addition, the above pricing includes packaging in compliant bulk containers and on-going routine stability testing costs, and is exclusive of all taxes, tariffs and customs duties.

* * * * *

Exhibit 3

PACKAGING SPECIFICATIONS

SAD will supply the Active Ingredient in packaging units of two (2) to three (3) kilograms for a purchased quantity below ten (10) kg and in packaging units of eight (8) to eleven (11) kilograms (standard preferred packaging unit) for a purchased quantity higher than ten (10) kilograms.

The following sizes of **[stainless steel]*** drums are utilized for packaging and delivery:

1. **[10L]*** drum - height*: **[273]***mm +/- **[3]***mm; Inside diameter: **[250]***mm +/- **[3]***mm, for**[2 - 3]***kg consignments.

2. **[35L]*** drum - height*: **[485]***mm +/- **[5]***mm, Inside diameter: **[315]***mm +/- **[3]***mm, for**[8 – 11]***kg of content (this drum is the standard pack).

* not factoring in the lid

SAD shall have the right, at its option, to deliver ordered quantities in one drum where feasible.

Exhibit 4

ACTIVE INGREDIENT SPECIFICATIONS

[REMAINDER OF PAGE REDACTED]*

Material Specification - CMC-FP-2006-14892 6.0
Insulin Human - HR1799

Specifications of **Insulin Human - HR1799 drug substance**

Test	Reference	Acceptance criteria
Appearance	Ph.Eur., USP	White to almost white crystalline powder
Identification - LC	Ph.Eur., USP	Rt(sample) = Rt(reference) ± 5 %
- Protease V8-digestion (LC)	Ph.Eur., USP	The profile obtained with the chromatogram of the test solution corresponds to that obtained with the reference solution (relative retention times ± 2 %)
Bioidentity[1]	USP	≥ 15 IU/mg [1]
Related Proteins - pre-HR 1798	Sanofi-Aventis	≤ 0.1 %
- Desamidoinsulin	Ph.Eur., USP Sanofi-Aventis	≤ 2.0 % L ≤ 1.0 % F
- Insulin-related Substances (IRS)	Ph.Eur., USP Sanofi-Aventis	≤ 2.0 % L ≤ 1.0 % F
High Molecular Weight Protein (HPSEC)	Ph.Eur., USP Sanofi-Aventis	≤ 1.0 % L ≤ 0.5 % F
Proinsulin-like Immunoreactivity	Ph.Eur.	≤ 10 ppm
E. coli Proteins [3]	Ph.Eur., USP	≤ 10 ppm
E. coli DNA[3]	Sanofi-Aventis	≤ 60 ppb
Proteolytic Activity [2]	Sanofi-Aventis	≤ 0.010 AU
Loss on Drying	Ph.Eur., USP	≤ 10.0 %
Residual Solvent [2] - 1-Propanol (GC)	Sanofi-Aventis	≤ 0.2 %
Sulphated Ash	Ph.Eur.	≤ 2.5 % [1]
Bacterial Endotoxins	Ph.Eur., USP	< 10 USP-EU/mg
Microbial Contamination	USP	≤ 300 aerobic microorganisms/g
Content Insulin (LC)	Ph.Eur. USP Sanofi-Aventis	95.0 to 105 % [1] ≥ 27.5 IU/mg [1] 27.5 to 30.3 IU/mg [1] (= 96.4 to 105.0 % of human insulin)
Content Zinc (AAS)	Ph.Eur., USP	≤ 1.0 % [1]

Abbreviations:
F: Release Limits
L: Shelf-life Limits
1) Calculated with reference to the dried substance
2) Removal proven by process validation data; not tested for batch release
3) Compliance with specification demonstrated for over 200 commercial batches; release testing is performed on every 10th batch

Specifications which are not designated with an "F" or "L" shall be valid for release and shelf-life testing.

Exhibit 5

MINIMUM PURCHASE COMMITMENTS

Generex shall purchase from SAD a minimum of [sixty (60)]* kilograms of Active Ingredient prior to December 31, 2011 as set forth below:.

Minimum quantity for the first three years of the agreement:

1. **Contract Year 1 (Effective Date through December 31, 2009): [10]* kg**
2. **Contract Year 2 (January 1, 2010 through December 31, 2010): [20]* kg**
3. **Contract Year 3 (January 1, 2011 through December 31, 2011): [30]* kg**

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Exhibit 6

IN-VITRO PHYSIO-CHEMICAL CHARACTERIZATIONS

In-Vitro Physio-Chemical Characterizations are determined using the following analytical methods:

- X-ray crystallography
- SDS-PAGE
- Mass-spectrometry
- FT-IR
- Loss on drying
- Impurity Profile (HPLC testing only)

Scientific comparisons from the results of these analytical techniques will be made to determine characterization equivalence between the SAD Active Ingredient and the third party supplying the active ingredient to Generex.. The characterization limits associated with loss on drying and impurity profile listed above are defined by USP and EU Pharmacopoeia set forth in Exhibit 4.